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Date of Submission: August 4, 2010

Selena Whitaker-Paquiet

Attorney Docket No. 89000.3013NP
PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re **Edward I. WULFMAN and Casey TORRANCE**

Group Art Unit : 3734

Application No.: 10/798,623

Filed : March 10, 2004

For : **LIQUID SEAL ASSEMBLY FOR A ROTATING TORQUE TUBE**

Examiner : Jennifer L. Hornberger

APPEAL BRIEF

MAIL STOP: Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Appellants **Edward I. WULFMAN** and **Casey TORRANCE**, by and through their attorney/agent of record, hereby submit this Appeal Brief.

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I. Real Party in Interest

The real party of interest for the subject application is Pathway Medical Technologies, Inc., the assignee of record.

II. Related Appeals and Interferences

Appellant is not aware of any prior or pending appeals, judicial proceedings or interferences which may be related, directly affect, be directly affected by or have a bearing on the Board's decision in the subject appeal.

III. Status of Claims

The status of the claims in the subject application is as follows:

Claim 1:	cancelled;
Claims 2-5:	rejected;
Claims 6-9:	cancelled;
Claim 10:	rejected;
Claims 11-16:	cancelled;
Claim 17:	rejected;
Claim 18:	cancelled;
Claims 19-27:	rejected;

Claims 2-5, 10, 17 and 19-27 are on appeal.

IV. Status of Amendments

An Amendment After Final Rejection was filed July 6, 2010 and was entered in an Advisory Action mailed July 16, 2010. The amendment cancelled claim 16 and made no other claim amendments.

V. Summary of Claimed Subject Matter

The present application discloses and claims an aspirating catheter device having a liquid seal assembly that provides an air-tight, substantially friction-free seal around a rotatable torque tube (e.g., a high speed rotational driveshaft) operating in proximity to an area of high vacuum. Providing a reliable, air-tight, low friction liquid seal around a high speed rotational driveshaft is challenging in general; it is particularly challenging when the driveshaft lacks a continuous, "solid" surface and is provided, for example, as a coiled structure having gaps between turns of the coiled structure. Conventional sealing mechanisms, such as O-rings, bushings and bearings, which are typically used to provide a liquid seal for a drive shaft, are prone to leakage and frictional heating as drive shafts of interventional catheters rotate, particularly at high rotational rates, during operation of the devices. The pending claims are directed to devices that use a liquid-filled liner as a sealing assembly at sealing sites, thereby eliminating the need to use conventional sealing mechanisms and providing an air-tight, substantially friction-free seal around the rotating torque tube.

All pending and finally rejected claims are on appeal; claims 19 and 20 are in independent format. Appellant argues the patentability of the following claims separately: claim 19, claim 20, claim 2 and claim 10.

Claim 19

Independent claim 19 is drawn to an aspirating catheter device including a liquid seal assembly (element 4 in Fig. 1 and element 20 in Fig. 2A) that uses a liquid confined in a liner surrounding the torque tube (liner element 24, illustrated in Figs. 2, 2B and 3) as a sealing medium to prevent air or other fluids from contacting the proximal area of a torque tube as described at page 4, lines 16-18 of the specification as filed, paragraph [0014] of the published application and page 6, lines 5-7 of the specification as filed, paragraph [0022] of the published application. More specifically, the claimed aspirating catheter device includes:

(a) a torque tube (element 10 in Fig. 1 and element 26 in Figs. 2A-D) operably connected to a drive system (element 8, illustrated in Fig. 1) that rotates the torque tube, as described in the specification as filed at page 6, lines 30-31, paragraph [0026] of the published application;

(b) a liner (element 24, illustrated in Figs. 2, 2B and 3) that surrounds the torque tube 26 as it enters an area of high vacuum in the area of the drive system to form a liquid flood space (element 44, illustrated in Figs. 2B and 3), as described in the specification as filed at page 7, lines 22-23 and at paragraph [0030] of the published application, and at page 8, lines 7-12 of the specification as filed, paragraph [0032] of the published application. As illustrated in Fig. 3, and described at page 11, lines 16-21 of the specification as filed, paragraph [0044] of the published application, the liner 24 extends longitudinally less than the length of the torque tube 26 and terminates distally at an intersect area P-P';

(c) an infusion port (element 40, illustrated in Fig. 2A) that supplies liquid to the liquid seal assembly 20 at an area of substantially atmospheric pressure, as described at page 8, lines 3-6 of the specification as filed , paragraph [0031] of the published application; and

(d) a catheter (element 6 in Fig. 1) that terminates at a proximal end in the sealing assembly (element 4 in Fig. 1, element 20 in Fig. 2A) at an aspiration site (element 38, illustrated in Fig. 2A), as described at page 7, line 29- page 8, line 2 of the specification as filed, paragraph [0030] of the published application, and that extends distally beyond intersect area P-P' thereby enclosing the liner 24, as illustrated in Fig. 3. As is conventional in the art, the catheter extends distally to enclose the torque tube and to enter a patient's body during use, as illustrated in Fig. 1 and described at page 6, lines 20-23 of the application as filed, paragraph [0024] of the published application, and forms an aspiration lumen (element 68) between the catheter and the liner 24, as illustrated in Figs. 2C, 2D and 3.

As described in the specification as filed at page 12, lines 7-12, paragraph [0047] of the published application, and shown in Fig. 2A, vacuum is applied to an aspiration port 60 provided in sealing assembly 20 during operation of the catheter device to remove matter from the body through aspiration lumen 68 and aspiration port 60. As illustrated in Fig. 3 and described at page 11, lines 16-21 of the application as filed, paragraph [0044] of the published application, liquid drawn into flood space 44 formed by liner 24 exits the flood space 44 at the intersect area P-P' and enters the aspiration lumen 68 directly at the intersect area. The liquid in the aspiration lumen, including the liquid drawn into flood space 44, subsequently exits the sealing assembly through aspiration port 60.

Claim 20

Independent claim 20 is drawn to a medical device comprising:

(a) a rotatable torque tube, such as a drive shaft (element 10 in Fig. 1 and element 26 in Figs. 2A-D) operably connected to a drive system (element 8, illustrated in Fig. 1) for rotation as described in the specification as filed at page 6, lines 30-31 , paragraph [0026] of the published application;

(b) a sealing assembly (element 20 in Fig. 2A) that includes:

(i) a housing (element 28 in Fig. 2A) that encloses a proximal portion of the torque tube 26 and a sealing site, as illustrated in Figs. 2A-E and described at page 7, lines 22-25 of the application as filed, paragraph [0030] of the published application;

(ii) a liner (element 24, illustrated in Figs. 2, 2B and 3) surrounding torque tube 26 and forming a flood space (element 44, illustrated in Figs. 2B and 3) that extends from a sealing site illustrated in Fig. 2B along a portion of the torque tube 26 to a distal end of the liner at an intersect area P-P' (Fig. 3), as described in the specification as filed at page 7, lines 22-23, paragraph [0030] of the published application and at page 8, lines 7-12 of the specification as filed, paragraph [0032] of the published application, and at page 11, lines 16-21 of the specification as filed, paragraph [0044] of the published application; and

(iii) an infusion port (element 40, illustrated in Fig. 2A) that supplies liquid to the flood space 44 at the sealing site as described at page 8, lines 3-6, of the specification as filed, paragraph [0031] of the published application; and

(c) a catheter (element 6 in Fig. 1) that terminates in the sealing assembly 20 at an aspiration site (element 38, illustrated in Fig. 2A), and extends beyond intersect area P-P' to enclose the liner 24 and that forms an aspiration lumen (element 68) between the catheter and the liner, as shown in Figs. 2C, 2D and 3, and as described at page 7, line 29- page 8, line 2 of the specification as filed, paragraph [0030] of the published application.

During operation of the device, liquid enters the flood space 44 at the sealing site and creates a liquid seal around the torque tube 26, thereby preventing the ingress of air into the torque tube and loss of vacuum at the proximal end of the sealing assembly. As illustrated in Fig. 3 of the application and described at page 11, lines 16-21 of the application as filed,

paragraph [0044] of the published application, the liquid exits the flood space 44 at the intersect site P-P', where it directly enters the aspiration lumen 68 and is withdrawn with the aspirate.

Claim 2

Claim 2 depends from claims 19 and 20 and specifies that the flood space (element 44, illustrated in Figs. 2B and 3) includes a clearance area between the liner and torque tube. This feature was described in claim 2 of the application as it was originally filed and is described at page 9, lines 19-21 of the specification as filed, paragraph [0037] of the published application.

Claim 10

Claim 10 depends from claims 19 and 20 and specifies that the sealing assembly comprises an overflow port for exit of excess liquid and wherein the torque tube extends through the overflow port. This feature was described in claim 10 of the application as it was originally filed, is illustrated as overflow port 56 in Fig. 2A, and is described at page 12, lines 1-6 of the specification as filed, paragraph [0046] of the published application.

VI. Grounds of Rejection to be Reviewed on Appeal

The grounds of rejection to be reviewed on appeal are as follows:

(a) whether claims 2/19-5/19, 2/20-5/20, 10, 17/19, 17/20, 19, 20, 22/19, 22/20, 23/19, 23/20, 26/19 and 26/20 are unpatentable under 35 U.S.C. §103(a) over Zacca et al. (US Patent 5,217,474) in view of Mische et al. (US Patent 5,490,859);

(b) whether claims 21/19, 21/20, 27/19 and 27/20 are unpatentable under 35 U.S.C. §103(a) over Zacca et al. (US Patent 5,217,474) in view of Mische et al. (US Patent 5,490,859) and further in view of Keith et al. (US Patent 5,938,670);

(c) whether claims 24/19 and 24/20 are unpatentable under 35 U.S.C. §103(a) over Zacca et al. (US Patent 5,217,474) in view of Mische et al. (US Patent 5,490,859) and further in view of Milo (US Patent 6,258,052); and

(d) whether claims 25/19 and 25/20 are unpatentable under 35 U.S.C. §103(a) over Zacca et al. (US Patent 5,217,474) in view of Mische et al. (US Patent 5,490,859) and Milo (US Patent 6,258,052) and further in view of Machold et al. (US Patent 4,976,720).

VII. Argument

Rejection of claims 2/19-5/19, 2/20-5/20, 10, 17/19, 17/20, 19, 20, 22/19, 22/20, 23/19, 23/20, 26/19 and 26/20 under 35 U.S.C. §103(a) as being unpatentable over US Patent 5,217,474 to Zacca et al. in view of US Patent 5,490,859 to Mische et al. cannot be sustained; Claims 2/19-5/19, 2/20-5/20, 10, 17/19, 17/20, 19, 20, 22/19, 22/20, 23/19, 23/20, 26/19 and 26/20 are patentable.

In the final Office Action mailed February 4, 2010, claims 2/19-5/19, 2/20-5/20, 10, 16/19, 16/20, 17/19, 17/20, 19, 20, 22/19, 22/20, 23/19, 23/20, 26/19 and 26/20 were finally rejected as being unpatentable over US Patent 5,217,474 to Zacca et al. ("Zacca et al.") in view of US Patent 5,490,859 to Mische et al. ("Mische et al."). Claim 16 has been cancelled and the rejection of claim 16 therefore is not considered on appeal. Appellants submit that this rejection cannot be sustained.

A claimed invention is unpatentable if the differences between it and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art. *Cross Medical Products, Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293 (Fed. Cir. 2005); *see* 35 U.S.C. § 103. A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984), MPEP §2141.02.

Claims 19, 3/19, 4/19, 5/19, 17/19, 22/19, 23/19 and 26/19

Independent claim 19 is drawn to an aspirating catheter device having a liquid seal assembly that uses a liquid-filled liner as a seal to prevent air or other fluids from contacting moveable catheter components in the area of a proximal end of a torque tube. The device comprises a torque tube operably connected to a drive system for rotation; a liner surrounding the torque tube as it enters an area of high vacuum in the area of the drive system to form a liquid flood space between the liner and the torque tube, the liner extending longitudinally less than the axial length of the torque tube and terminating distally at an intersect area; an infusion port

supplying liquid to the liquid seal assembly at an area of substantially atmospheric pressure; and a catheter having a proximal end terminating in the sealing assembly at an aspiration site and extending distally to enclose the torque tube and the liner; wherein the catheter extends distally beyond the intersect area with respect to an operator of the device and forms an aspiration lumen between the catheter and the liner. As stated in the claim, liquid drawn into the flood space during operation of the catheter system exits the flood space at the intersect area and enters the aspiration lumen directly at the intersect area. In other words, liquid exits the flood space formed by the liner and is drawn into the aspiration lumen and aspirated without exiting the device. Claims 3/19, 4/19, 5/19, 17/19, 22/19, 23/19 and 26/19 all depend from claim 19.

With regards to independent claim 19, the Examiner asserted that US Patent 5,217,474 to Zacca et al. ("Zacca et al.") discloses a medical device comprising:

> *"a torque tube (8) operably connected to a drive system (1) for rotation; a liner (14) surrounding the rotatable torque tube to form a liquid flood space (34) between the liner and the torque tube, wherein proximal portions of the torque tube and the liner are positioned in a housing (9) in a manner that permits free rotation and axial translation of the torque tube; the liner (14) extending longitudinally less than the axial length of the torque tube and terminating at an intersect area (Fig. 1); an infusion port (3) supplying liquid to the liquid seal assembly at an area of substantially atmospheric pressure (col. 6, ln. 44-46), whereby liquid drawn into the flood space during operation of the catheter system exits the flood space at the intersect area".*

The Examiner also stated that:

> *"Zacca et al. fail to disclose an aspiration catheter having a proximal end terminating in the sealing assembly at an aspiration site and extending distally to enclose the torque tube and liner and beyond the intersect area with respect to the operator, the catheter forming an aspiration lumen between the catheter and the liner".*

With regards to Mische et al., the Examiner asserted that:

> *"Mische et al. disclose an aspiration catheter (90) having a proximal end terminating in a sealing assembly at an aspiration site (port 82) and extending distally to enclose a torque tube (94) having a liner (100; col. 11, ln. 24-35; col. 25, ln. 32-36), Mische et al. further discloses that fluid is provided through the drive shaft and or through the liner (100) and fluid drawn into the flood space during operation of the catheter system exists the flood space at the intersect area and enters the aspiration lumen."*

The Examiner additionally stated:

> *"It would have been obvious to one of ordinary skill in the art to modify the medical device of Zacca et al. to include an aspiration catheter having a proximal end terminating in the sealing assembly and extending distally to enclose the torque tube and the liner to form an aspiration lumen between the catheter and liner as suggested by Mische et al. in order to remove the particulate from the body. Mische et al. disclose the location that fluid exits the liner or the "intersect area" is predetermined by appropriately choosing the length of the liner (100) (col. 25, ln. 32-36). Therefore it would have been obvious to one of ordinary skill in the art to choose the length of the liner, such that it terminates before the distal end of the aspiration catheter, based on desired location for fluid to exit the liner",*

and further stated:

> *"Zacca et al. modified by Mische et al. disclose the liner (14) surrounding the torque tube (8) as it enters an area of high vacuum in the area of the drive system and the aspiration catheter extending distally beyond the intersect area, such that liquid exiting the liner at the intersect area directly enters the aspiration lumen."*

Zacca et al. describe an atherectomy device having an adjustable diameter coil tip 16 attached to the distal end of a drive shaft coil 8. The drive shaft coil 8 rotates within a catheter 14 (col. 5, lines 45-46 and 56-58; Figs. 1 and 2). At col. 6, lines 4-8, Zacca et al. state that flexible catheter 14 "protects the body's intervening vasculature from injury or trauma during rotation of the drive shaft". It is thus clear that flexible catheter 14 forms the outer most surface of the device of Zacca et al. and is not equivalent to the liner recited in independent claim 19 but is, at best, similar to the "catheter" recited in lines 9-10 of claim 19.

Zacca et al. also disclose the injection of a contrast medium or cooling fluid through a central lumen and annular space located between the outer surface of the drive shaft and the inner surface of the outer catheter. The infused fluids exit the catheter/drive shaft system at a distal region to inject a contrast medium, medication or the like to the site of intervention, or to cool the coil tip at the site of intervention. (*See, e.g.,* Col. 6, lines 24-52.) Appellants do not perceive that Zacca et al. disclose how the drive shaft coil 8 is sealed with respect to its housing to prevent air and/or fluid leakage.

Thus there is no teaching or suggestion in the disclosure of Zacca et al. of a liner that surrounds the torque tube and forms a liquid flood space between the liner and the torque tube

and extends longitudinally less than the axial length of the torque tube as clearly recited in claim 19. Furthermore, Zacca et al. do not teach or suggest that catheter 14 encloses a liner and forms an aspiration lumen between the liner and the catheter, as recited in line 12 of claim 19. Indeed, appellants have been unable to find any reference to aspiration in the disclosure of Zacca et al.

Mische et al. describe an intravascular material removal device including an expandable material removal element 16 positioned at the distal end of a catheter assembly 14 and a drive assembly 12 connected to the catheter assembly 14 by a manifold assembly 22 (col. 4, line 66 – col. 5, line 6 and Fig. 1). Material removal element 16 can be moved between a contracted position and an expanded position by means of a guidewire 42 (col. 6, lines 12-16), and can be rotated by means of a drive shaft 92 that extends through catheter assembly 14 (col. 5, lines 58-61). A fluid seal 43, such as a diaphragm and the like, is provided at the proximal end 32 of the drive shaft so that fluid within the drive shaft 26 cannot leak into the interior of the housing. The fluid seal, however, allows the guidewire to extend from the drive shaft into the inner sheath. (Col. 5, lines 51-57.) In another embodiment, a pair of fluid seals, 84 and 86, are provided extending from the main lumen on opposites of the port to form a fluid-tight seal around a portion of the drive shaft. (*See, e.g.,* Col. 10, lines 12-40 and Fig. 1, components 84, 86.) An aperture is provided in the drive shaft, between the seals, allowing fluid to pass into the interior of the drive shaft and providing infusion for lubrication and for irrigation. These seals are not described in detail, but they appear to be conventional O-ring or bushing-type seals.

Mische et al. also disclose a manifold assembly 22 including a port 82 that communicates with a catheter sheath 90 connected to the distal end of manifold assembly 22 and that can be used to deliver fluids for infusion or negative pressures for aspiration (col. 10, lines 30-40, Fig. 1). At col. 11, lines 24-39, Mische et al. teach that a coating 100 can be applied to the outer surface of the drive shaft 92 to reduce friction between the outer surface of the drive shaft 92 and the inner surface of the catheter sheath 90. Specifically, Mische et al. state that "the coating 100 may be provided in the form of a sheath of a fluoropolymer which shrinks upon application of heat". Coating 100 is provided in order to "improve trackability", "reduce friction between the outer surface of the drive shaft 92 and the inner surface of the catheter sheath 90" and "insure proper aspiration through the catheter sheath 90 by minimizing friction between the drive shaft 92 and occlusion material aspirated into the catheter sheath 90". There is no teaching or

suggestion in Mische et al. that coating 100 provides a liquid flood space between the drive shaft and the coating.

At col. 25, lines 18-37, Mische et al. state that a fluid such as saline can be provided through a port 80 "into the hollow interior of the drive shaft 92". The fluid then flows through drive shaft 92 into the hollow interior of material removal element 16 and exits removal element 16 in order to "infuse the intravascular treatment site with fluid". The reference teaches that the length of the coating 100 can be selected in order to predetermine "the location at which the fluid exits the drive shaft 92", and continues to state that the infusion of fluid "may provide for maintenance of fluid within a vascular lumen if aspiration is used". Given that the stated goal of infusing a liquid through the interior of drive shaft 92 is to maintain fluid in the vascular lumen during aspiration, one would clearly not select the length of coating 100 such that it terminates distally at an area where fluid exiting the drive shaft directly enters an aspiration lumen as recited in independent claim 19. Indeed, at col. 11, lines 39-45, Mische et al. state that "catheter sheath 90 terminates at a location offset proximally of the distal end 98 of the drive shaft 92 and a proximal end for the material removal element 16", and that this "provides for proper irrigation and aspiration of an intravascular treatment site *because the irrigation site is located distally of the aspiration site*" (emphasis added). Thus Mische et al. clearly teach away from an aspirating catheter device including an aspiration lumen and a liner surrounding a torque tube that forms a liquid flood space between the liner and the torque tube, wherein the liner extends longitudinally less than the axial length of the torque tube and terminates distally at an intersect area whereby liquid exits the flood space at the intersect area and enters the aspiration lumen directly at the intersect area as recited in present claim 19.

Appellants find no motivation, in either of the references or in the knowledge generally available to one of ordinary skill in the art, to combine the teachings of Zacca et al. and Mische et al., or to modify the references to provide the subject matter of independent claim 19. Specifically, combining the disclosure of Zacca et al. with that of Mische et al. would not provide an aspirating catheter device including (a) a torque tube, (b) a liner surrounding the torque tube to form a liquid flood space between the liner and the torque tube, wherein the liner extends longitudinally less than the axial length of the torque tube and terminates distally at an intersect area, and (c) a catheter that encloses the torque tube and the liner, *extends distally beyond the*

intersect area, and forms an aspiration lumen between the catheter and the liner, whereby liquid exits the flood space at the intersect area and *enters the aspiration lumen directly at the intersect area*, as recited in claim 19.

Furthermore, not only would combining the teachings of Zacca et al. and Mische et al. not provide the subject matter recited in claim 19, but the teachings of Zacca et al. and Mische et al. in fact teach away from the subject matter of claim 19. The infusion and/or aspiration system(s) disclosed in these references are provided for delivering fluids to the site of an intervention, or removing materials from the site of an intervention. To modify the components to deliver fluids to an aspiration lumen located proximal to the tip of the rotating device so that fluids are aspirated without being delivered to the site of the intervention runs counter to any rational interpretation of the teachings of these references. The rejection of claim 19 thus cannot be sustained.

Claims 3/19, 4/19, 5/19, 17/19, 22/19, 23/19, and 26/19 depend from independent claim 19 and thus encompass all the limitations of claim 19. It follows that as the teachings of Zacca et al. and Mische et al. would not have rendered the subject matter of independent claim 19 obvious to one of skill in the art at the time the invention was made, the rejection of claims 3/19, 4/19, 5/19, 17/19, 22/19, 23/19 and 26/19 under 35 USC §103 also cannot be sustained. Appellants submit that these claims are allowable.

Claims 20, 3/20, 4/20, 5/20, 17/20, 22/20, 23/20 and 26/20

Independent claim 20 is drawn to a medical device comprising (a) a rotatable torque tube connected to a drive system, (b) a sealing assembly comprising (i) a housing that encloses a proximal portion of the torque tube and a sealing site, (ii) a liner surrounding the torque tube and forming a flood space that extends from the sealing site along at least a portion of the torque tube and terminates distally at an intersect area, and (iii) a infusion port that provides liquid to the flood space at the sealing site; and (c) a catheter terminating in the sealing assembly at an aspiration site and extending distally beyond the intersect area to enclose the liner that forms as aspiration lumen between the catheter and the liner, whereby liquid enters the flood space at the sealing site and creates a liquid seal around the torque tube to prevent ingress of air and wherein

the liquid exits the flood space at the intersect area where it directly enters the aspiration lumen.

Claims 3/20, 4/20, 5/20, 17/20, 22/20, 23/20 and 26/20 all depend from claim 20.

With regards to Zacca et al. as it relates to independent claim 20, the Examiner asserts:

> *"Zacca et al. disclose a medical device comprising: a rotatable torque tube (8) operably connected to a drive system (1) for rotation; a sealing assembly comprising: a housing (9) enclosing at least a proximal portion of the torque tube (8) and a sealing site; a liner (14) surrounding the torque tube (8) and forming a flood space (34) extending from the sealing site along at least a portion of the torque tube to an intersect area; and an infusion port (3) providing application of liquid to the flood space at the sealing site during operation of the device (col. 6, ln. 44-46; Fig. 1), whereby during operation of the medical device liquid enters the flood space formed by the liner at the sealing site and creates a liquid seal around the torque tube to prevent ingress of air, the liquid exiting the flood space at the intersect area."*

The Examiner notes that:

> *"Zacca et al fail to disclose an aspiration catheter terminating in the sealing assembly at an aspiration site and extending distally beyond the intersect area to enclose the liner."*

With regards to Mische et al., the Examiner states:

> *"Mische et al. disclose an aspiration catheter (90) enclosing a torque tube (94) having a liner (100; col. 11, ln. 24-35; col. 25, ln. 32-36). Mische et al further discloses that fluid is provided through the drive shaft and or through the liner (100) and fluid drawn into the flood space during operation of the catheter system exits the flood space at the intersect area and enters the aspiration lumen.*

The Examiner then asserts that:

> *"It would have been obvious to one of ordinary skill in the art to modify the medical device of Zacca et al. to include an aspiration catheter having a proximal end terminating in the sealing assembly and extending distally to enclose the torque tube and the liner to form an aspiration lumen between the catheter and the liner as suggested by Mische et al. in order to remove the particulate from the body. Mische et al. disclose the location that fluids exits the liner or the "intersect area" is predetermined by appropriately choosing the length of the liner (100) (col. 25, ln. 32-36). Therefore it would have been obvious to one of ordinary skill in the art to choose the length of the liner such that it terminates before the distal end of the aspiration catheter, based on desired location for fluid to exit the liner.*

In concluding, the Examiner asserts:

"Zacca et al. modified by Mische et al. disclose the aspiration catheter extending distally beyond the intersect area, such that liquid exiting the liner at the intersect area directly enters the aspiration lumen."

The teachings of Zacca et al. and Mische et al. are discussed in detail above. Appellants have been unable to find any evidence or suggestion of the subject matter of claim 20 as a whole in these cited references. Specifically, neither Zacca et al. nor Mische et al., taken either singly or in combination, teach or suggest a medical device having a liner surrounding a torque tube and forming a flood space that terminates distally at an intersect and a catheter enclosing the liner that terminates distally beyond the intersect area and forms an aspiration lumen between the catheter and the liner, whereby liquid enters the flood space to create a liquid seal around the torque tube to prevent the ingress of air, and both exits the flood space and directly enters the aspiration lumen at the intersect area. Indeed, neither Zacca et al. nor Mische et al. address the problem of preventing the ingress of air into a torque tube. Furthermore, as discussed above, Mische et al. actually teach away from a medical device as recited in claim 20 wherein a catheter surrounding a liner and forming an aspiration lumen between the catheter and the liner extends *beyond* a distal end of the liner such that fluid exiting the distal end of the liner directly enters the aspiration lumen and is aspirated without being delivered to a rotating tip or a site of intervention. Thus the rejection of independent claim 20 cannot be sustained.

Claims 3/20, 4/20, 5/20, 17/20, 22/20, 23/20 and 26/20 depend from independent claim 20 and thus encompass all the limitations of claim 20. It thus follows that, as the teachings of Zacca et al. and Mische et al. would not have rendered the subject matter of independent claim 20 obvious to one of skill in the art at the time the invention was made, the rejection of claims 3/20, 4/20, 5/20, 16/20, 17/20, 22/20, 23/20 and 26/20 under 35 USC §103, cannot be sustained. Appellants submit these claims are allowable.

Claim 2

The patentability of claim 2 is argued separately. Claim 2 depends from independent claims 19 and 20 and is drawn to the aspirating catheter device of claim 19 and the medical device of claim 20 wherein the flood space includes a clearance area between the liner and the torque tube.

The disclosures of Zacca et al. and Mische et al., as they pertain to independent claims 19 and 20, are discussed in detail above. The Examiner asserts that Zacca et al. "disclose the flood space (34) includes a clearance area between the liner and the torque tube." However, as discussed above, element 14 of Zacca et al. is not equivalent to the liner of the present claims but is in fact an outer catheter. Thus Zacca et al. do not teach or suggest a clearance area between a liner and the torque tube.

Furthermore, Mische et al. do not teach or suggest a clearance area between coating 100 and the outer surface of drive shaft 92. Indeed Mische et al. state that the coating "is applied to the outer surface of the drive shaft", indicating that the coating directly contacts the outer surface of the drive shaft. Mische et al. therefore teach away from Appellants' claim 2/20. In light of this teaching, the Examiner's proposed combination and the resulting rejection cannot be sustained.

There is no evidence or suggestion of the subject matter of claim 2 in either Zacca et al. or Mische et al. Accordingly, the disclosures of Zacca et al. and Mische et al. would not have rendered the subject matter of claim 2 obvious to one of ordinary skill in the art at the time the present invention was made, and the rejection of claim 2 cannot be sustained.

Claim 10

Claim 10 depends from independent 20 and additionally specifies that the sealing assembly comprises an overflow port for exit of excess liquid and provides that the torque tube extends through the overflow port.

The disclosures of Zacca et al. and Mische et al., as they pertain to claim 20, are discussed in detail above. The Examiner asserts that "Zacca et al. disclose the sealing member further comprises an overflow port for exit of excess liquid and wherein the torque tube extends through the overflow port" without providing any citation to Zacca et al. or what one of ordinary skill in the art would understand in light of the disclosure of Zacca et al. Zacca et al. disclose the injection of a contrast medium or cooling fluid through a port 3 (See, e.g., Col. 6, lines 44-53) in the drive-control unit 9 but do not disclose an overflow port or disclose the torque tube extending through the overflow port. Zacca et al. disclose that flexible catheter tubes 38 and 40 extend proximally within the passage created by drive shaft coil 8 beyond the proximal end of the drive

shaft coil within the control unit. This teaching suggests to Appellants that if Zacca et al. incorporated an overflow port, it would be positioned proximal to the proximal end of the drive shaft coil, which teaches against the arrangement specified in claim 10/20.

The Examiner does not mention Mische et al. with respect to the subject matter of claim 10, and Appellants perceive no disclosure in Mische et al. relating to an overflow port or the location of a drive shaft coil with respect to an overflow port. Appellants submit that there is no evidence or suggestion of the subject matter of claim 10 in either Zacca et al. or Mische et al. Accordingly, the subject matter of claim 10 would not have been obvious to one of ordinary skill in the art at the time the invention was made, and the rejection of claim 10 cannot be sustained.

Rejection of claims 21/19, 21/20, 27/19 and 27/20 under 35 U.S.C. §103(a) as being unpatentable over US Patent 5,217,474 to Zacca et al. in view of US Patent 5,490,859 to Mische et al. and further in view of US Patent 5,938,670 to Keith et al. cannot be sustained; Claims 21/19, 21/20, 27/19 and 27/20 are patentable.

Claims 21/19, 21/20, 27/19 and 27/20 stand finally rejected as being unpatentable over US Patent 5,217,474 to Zacca et al. ("Zacca et al.") in view of US Patent 5,490,859 to Mische et al. ("Mische et al.") and further in view of US Patent 5,938,670 to Keith et al. ("Keith et al."). Specifically, the Examiner asserted:

> *"It would have been obvious to one of ordinary skill in the art to dimension the diameter and the length of the liner of Zacca et al. to provide more resistance to fluid flow, thereby reduce pressure within the flood space and reduce the rate of fluid flow along the length of the liner as taught by Keith et al. to provide more effective cooling of the drive shaft coil."*

Claim 21 specifies that the pressure within the flood space decreases along the length of the liner in a distal direction during operation of the device. Claim 27 specifies that the length and diameter of the liner forming the flood space are selected to reduce the rate of flow in the proximal to distal direction in the flood space and reduce the requirement for precise diametrical tolerances during operation of the device.

The disclosures of Zacca et al. and Mische et al., and their deficiencies with respect to claims 19 and 20, are discussed above. Keith et al. does not overcome these deficiencies. As

claims 21 and 27 depend from independent claims 19 and 20, they necessarily include all the limitations of claims 19 and 20. Accordingly, the subject matter of claims 21 and 27 would not have been rendered obvious to one of ordinary skill in the art by Zacca et al., Mische et al., and/or Keith et al., and therefore this rejection cannot be sustained. Appellants submit these claims are allowable.

Rejection of Claims 24/19 and 24/20 under 35 U.S.C. §103(a) as being unpatentable over US Patent 5,217,474 to Zacca et al. in view of US Patent 5,490,859 to Mische et al. and further in view of US Patent 6,258,052 to Milo cannot be sustained; Claims 24/19 and 24/20 are patentable.

Claims 24/19 and 24/20 stand finally rejected as being unpatentable over US Patent 5,217,474 to Zacca et al. ("Zacca et al.") in view of US Patent 5,490,859 to Mische et al. ("Mische et al.") and further in view of US Patent 6,258,052 to Milo ("Milo"). Specifically, the Examiner asserted:

> *"Zacca et al. is silent as to the material of the liner (14). Milo discloses a polyimide tube in contact with a coiled wire or shaft increases pushability and column strength (col. 2, ln. 61-col. 3, ln. 2). It would have been obvious to one of ordinary skill to have tried making the liner of polyimide tubing to provide the same advantages to the coiled torque tube of Zacca et al. to prevent buckling during operation."*

Claim 24 recites a device of any one of claims 19 and 20 wherein the liner comprises a thin, tough, flexible polymer-based tubing material.

Milo discloses a guidewire for crossing vascular occlusions comprising a guidewire shaft, a drive member rotatably disposed within and along a longitudinal axis of the guidewire shaft, an actuator connected to a proximal end of the drive member, and an asymmetrical rotating tip attached to a distal end of the drive member. The reference teaches that the guidewire shaft may include a coiled wire and a polymeric tube formed, for example, from polyimide. The disclosures of Zacca et al. and Mische et al., and their deficiencies with respect to claims 19 and 20, are discussed above. Milo does not overcome these deficiencies. As claim 24 depends from independent claims 19 and 20, it necessarily includes all the limitations of claims 19 and 20.

Accordingly, the subject matter of claim 24 would not have been rendered obvious to one of ordinary skill in the art by Zacca et al., Mische et al., and/or Milo, and therefore this rejection cannot be sustained. Appellants submit claim 24 is allowable.

Rejection of Claims 25/19 and 25/20 under 35 U.S.C. §103(a) as being unpatentable over US Patent 5,217,474 to Zacca et al. in view of US Patent 5,490,859 to Mische et al. and US Patent 6,258,052 to Milo, and further in view of U.S. Patent 4,976,720 to Machold et al,. cannot be sustained; Claims 25/19 and 25/20 are patentable.

Claims 25/19 and 25/20 stand finally rejected as being unpatentable over US Patent 5,217,474 to Zacca et al. ("Zacca et al.") in view of US Patent 5,490,859 to Mische et al. ("Mische et al.") and US Patent 6,258,052 to Milo ("Milo") as applied to claim 24, and further in view of U.S. Patent 4,976,720 to Machold et al. ("Machold et al."). Specifically, the Examiner asserted:

> *"Zacca et al. in view of Mische et al. and Milo fail to disclose a lubricious coating. Machold et al. disclose a polyimide tube having a lubricious coating (col. 5, ln. 3-4). It would have been obvious to one of ordinary skill in the art provide a lubricious coating on the polyimide liner to reduce friction between the aspiration catheter and the liner."*

Claim 25 recites a device of claim 24, wherein the liner comprises polyimide tubing and has a lubricious coating.

The disclosures of Zacca et al., Mische et al. and Milo, and their deficiencies with respect to claim 24, are discussed above. Machold et al. disclose a dilatation catheter having an inner tubular member formed of polyimide tubing provided with an inner lubricious lining. The teachings of Machold et al. do not overcome the deficiencies of Zacca et al., Mische et al. and Milo. As claim 25 depends from claim 24, it necessarily includes all the limitations of claim 24. The subject matter of claim 25 would therefore not have been rendered obvious to one of ordinary skill in the art at the time the present invention was made by Zacca et al., Mische et al., Milo, and/or Machold et al. and the rejection of claims 25/19 and 25/20 cannot be sustained. Appellants submit these claims are allowable.

Conclusion

Appellants submit that all of the pending claims are allowable; allowance of all the pending claims on appeal is respectfully requested.

Respectfully submitted,

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VIII. Claims Appendix

Claim 1 **(cancelled)**.

Claim 2 **(rejected)**: The device of any one of claims 19 and 20, wherein the flood space includes a clearance area between the liner and torque tube.

Claim 3 **(rejected)**: The device of any one of claims 19 and 20, wherein the torque tube is a coiled drive shaft and the flood space includes gaps between the coils.

Claim 4 **(rejected)**: The device of any one of claims 19 and 20, wherein the torque tube includes a lumen for a guide wire and the flood space includes the lumen.

Claim 5 **(rejected)**: The device of claim 19 or 20, further comprising a suction port for aspirating fluid from the aspiration lumen and wherein the pressure in the flood space is lower than the pressure outside or proximal to the flood space during operation of the device.

Claims 6-9 **(cancelled)**.

Claim 10 **(rejected)**: The device of claim 20, wherein the sealing assembly comprises an overflow port for exit of excess liquid and wherein the torque tube extends through the overflow port.

Claims 11-16 **(cancelled)**.

Claim 17 **(rejected)**: The device of any one of claims 19 and 20, wherein proximal portions of the rotatable torque tube and liner are positioned in a hand held unit.

Claim 18 **(cancelled)**.

Claim 19 **(rejected)**: An aspirating catheter device having a liquid seal assembly that uses liquid as a sealing medium to prevent air or other fluids from contacting moveable catheter components in the area of a proximal end of a torque tube, the aspirating catheter device comprising: a torque tube operably connected to a drive system for rotation; a liner surrounding the torque tube as it enters an area of high vacuum in the area of the drive system to form a liquid flood space between the liner and the torque tube, the liner extending longitudinally less than the axial length of the torque tube and terminating distally at an intersect area; an infusion port supplying liquid to the liquid seal assembly at an area of substantially atmospheric pressure; and a catheter having a proximal end terminating in the sealing assembly at an aspiration site and extending distally to enclose the torque tube and the liner, wherein the catheter extends distally beyond the intersect area with respect to an operator of the device and forms an aspiration lumen between the catheter and the liner; whereby liquid drawn into the flood space during operation of the catheter system exits the flood space at the intersect area and enters the aspiration lumen directly at the intersect area.

Claim 20 **(rejected)**: A medical device comprising:

(a) a rotatable torque tube operably connected to a drive system for rotation;

(b) a sealing assembly comprising:

(i) a housing enclosing at least a proximal portion of the torque tube and a sealing site;

(ii) a liner surrounding the torque tube and forming a flood space extending longitudinally from a the sealing site along at least a portion of the torque tube to a distal terminal end of the liner at an intersect area; and

(ii) an infusion port providing application of liquid to the flood space at the sealing site during operation of the device; and

(c) a catheter terminating in the sealing assembly at an aspiration site and extending distally beyond the intersect area to enclose the liner and forming an aspiration lumen between the catheter and the liner,

whereby, during operation of the medical device, liquid enters the flood space formed by the liner at the sealing site and creates a liquid seal around the torque tube to prevent ingress of air, the liquid exiting the flood space at the intersect area, where it directly enters the aspiration lumen.

Claim 21 **(rejected)**: The device of claim 19 or 20, wherein pressure within the flood space decreases along the length of the liner in a distal direction during operation of the device.

Claim 22 **(rejected)**: The device of any one of claims 19 and 20, wherein the inner diameter of the liner is from about 0.030 to about 0.040 inch.

Claim 23 **(rejected)**: The device of any one of claims 19 and 20, wherein the length of the liner is more than about 6 inches.

Claim 24 **(rejected)**: The device of any one of claims 19 and 20, wherein the liner comprises a thin, tough, flexible polymer-based tubing material.

Claim 25 **(rejected)**: The device of claim 24, wherein the liner comprises polyimide tubing and has a lubricious coating.

Claim 26 **(rejected)**: The device of any one of claims 19 and 20, wherein proximal portions of the torque tube and liner are positioned in a housing in a manner that permits free rotation and axial translation of the torque tube.

Claim 27 **(rejected)**: The device of any one of claims 19 and 20, wherein the length and diameter of the liner forming the flood space are selected to reduce the rate of flow in the proximal to distal direction in the flood space and reduce the requirement for precise diametrical tolerances during operation of the device.

IX. Evidence

None.

X. Related Proceedings

None.